September 9, 1998

This document was submitted to EPA by a registrant in connection with EPA's evaluation of this chemical and it is presented here exactly as submitted.

42/OPP# 34134

Bayer

**Agriculture Division**

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August 11, 1998



Karen Angulo
Special Review and Reregistration Division, H7508W
Office of Pesticide Programs
Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460-0001

Subject: NEMACUR (Fenamiphos)
EPA Chemical No. 100601
Health Effects Division 1994 Science Chapter
Environmental Fate and Effects Divisions 1994 Science Chapter
OPP Docket No. 34130

Dear Mrs. Angulo:

Bayer Corporation received the Environmental Fate and Effects Division (EFED) 1994 Science Chapter and an advance copy of the Health Effects Division (HED) 1994 Science Chapter in the fall of 1994. Since that time, Bayer has continued to develop data in support of fenamiphos for all labeled uses and tolerances except soybeans and cocoa. Bayer is also currently supporting uses pending with the EPA which include broccoli, cauliflower, cantaloupe, coffee, etc.

The EFED 1994 Science Chapter recommended that Bayer propose mitigation measures which would address groundwater concerns and hazards to non-target organisms. In addition, data gaps for leaching/adsorption/desorption, terrestrial field dissipation, and groundwater monitoring were addressed. The required studies are currently underway. The last study to be completed will be a California groundwater monitoring study which is scheduled to be submitted to the EPA in 2001.

In addition to product stewardship measures proposed previous to this science chapter, Bayer has since offered additional rate limiting and stewardship measures to address groundwater concerns and hazards to non-target organisms. These measures include: 1) reduce the rate per application on apple, cherry, nectarine, peach, grape, citrus and pineapple; 2) reduce the amount of product which can be applied per season on apple, cherry, nectarine, peach, grape, citrus, kiwifruit and pineapple; 3) reduce the number of applications per season on apple, cherry, nectarine, peach, citrus and kiwifruit; 4) limit the number of applications to grapes; 5) extend the interval between applications on apple, cherry, nectarine, peach, grape and citrus; 6) replace broadcast applications with band applications on pineapple; 7) cancel use of Nemacur 15% Granular on citrus; 8) add statements to the label to reduce risk from runoff on erodible soils; 9) establish vegetative buffers and setbacks from aquatic habitats; 10) add restrictions to minimize runoff from golf courses; and 11) restrict use on citrus in Florida to certain counties. These proposals have been accepted by the EPA and are currently on our EPA registered product labels.

The 1994 HED Science Chapter addressed product chemistry, dietary (residue chemistry), occupational and residential exposure, post application/re-entry exposure, personal protective equipment (PPE) and chronic dietary issues. Since this 1994 HED Science Chapter was issued, facts have changed. For example, due to the revision of EPA's Table 1. - Raw Agricultural and Processed Commodities and Feedstuffs Derived From Crops, fenamiphos meat and milk tolerances are no longer required based on an HED's 5/14/96 memorandum. In addition, HED has determined that the appropriate endpoint for acute dietary analysis should now be 0.37 mg/kg/day and a margin of exposure (MOE) of 300 is required to ensure protection of infants and children as required by FQPA. Both of these facts affect EPA's acute dietary exposure assessment contained in HED's October 28, 1994 memorandum. Bayer has since submitted an acute dietary Monte Carlo analysis showing an acceptable MOE of greater than 300 for all population subgroups at the 99.9 percentile.

We recently have been informed that EPA has prepared 1996 and 1998 science chapters, which have not been distributed outside the Agency. Since significant changes have occurred in label recommendations since 1994, a current, fair and accurate assessment can not be made on science chapters we have not seen. It is also Bayer's position that the interested stakeholders should not be drawing conclusions or making comments on the 1994 science chapters in the public docket since the information summarized there is outdated and incomplete.

If you have any questions concerning this submission, please contact Mr. Melvin Tolliver of my staff at (816) 242-2150.

Sincerely,

BAYER CORPORATION
AGRICULTURE DIVISION

Melvin K. Tolliver

for

John S. Thornton
Director, Product Registrations
and Regulatory Affairs

MKT:afv